dertaken to better understand the factors influencing the funding decisions. **RESULTS:** During this period three submissions were considered under the RoR criteria, two in 2008 and one in 2009. None of these were approved for listing on the basis of the RoR, however two were accepted on the basis of high clinical need and high but acceptable cost-effectiveness ratio. No submission has requested consideration under the RoR, or been assessed under this criteria by the PBAC, since November 2009. In comparison, from 2008-2011, 4 new applications and 5 re-submissions requested listing on the LSDP and 3 of these were successful. **CONCLUSIONS:** Despite stricter criteria for the LSDP than the RoR, applications to the LSDP have had a better success rate. The RoR has not been used to justify a listing on the PBS for at least four years, perhaps indicating that these criteria are no longer favoured by the PBAC.

### PHP11

### RESULTS OF RESOLUTION OF BRAZILIAN CHAMBER OF ECONOMIC REGULATION OF PHARMACEUTICALS N° 2 /2004

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**OBJECTIVES:** In Brazil, the concepts of minimization cost are being applied in price analyses of new pharmaceuticals since 2004, when was published the Resolution of Brazilian Chamber of Economic Regulation of Pharmaceuticals (CMED) n° 2/2004. The drugs are divided in two types: new drugs presentations and new molecules, these are classified by two categories: I - New product with patent of molecule, which has scientific evidences of benefits over the medications used on the same treatment; II - New products which were not classified as category I. The prices analyses of new drugs are classified by two methods the lowest international price and cost of treatment considering an existing medication traded in Brazil. The category I take in the consideration the lowest international price and the category II considering the cost of treatment and international price, the lowest of them. The goal of this research is to evaluate the price regulation of new molecules over the last eight years and all the consequences in terms of prices and a decrease of costs for the society. **METHODS:** Only data of prices analyses assessed by Office of Economic Assessment of New Technologies of Brazilian Health Surveillance Agency (Anvisa), which supports the decisions of CMED, were evaluated. **RESULTS:** According to our statistics, 209 new molecules - category I and II - (over 563 presentations) were analyzed. During the last eight years, the difference between the price proposed by the laboratories and the price analyzed by Anvisa has been reduced, as demonstrated bellow: Category I 21%; Category II 39%. **CONCLUSIONS:** It suggests the prices are more in conformity of the resolution. In fact, the Resolution CMED n° 2/2004 brought rational price decrease and, in consequence, cost decrease for the private and public sector, improving the efficiency of health care.

### PHP12

### SHORTAGES OF SYSTEMIC ANTIBIOTICS IN THE UNITED STATES: A PUBLIC HEALTH CONCERN

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**OBJECTIVES:** Shortages of antibiotics adversely impact health outcomes and health care costs. We assessed the prevalence of shortages of systemic antibiotics and evaluated the characteristics of the antibiotics in short supply as reported by federal agencies and private health care providers in the US on June 1, 2011. **METHODS:** Data were collected from the FDA, American Society of Health-System Pharmacists (ASHP), and Brigham and Women's Hospital (BWH) websites. The units of analysis were active ingredient(s) and route of administration. The prevalence of shortages was estimated as a percentage of the total number of products in the US market as of June 1, 2011. **RESULTS:** A total of 18 antibiotic active ingredients with 20 routes of administration were in short supply as of June 1st, 2011. The prevalence of shortages of systemic antibiotics varied from 20.6% reported by ASHP to 3.1% reported by the FDA and BWH. Injectable antibiotics had the highest (28.3%) rate of shortage followed by oral products (11.4%). Three shortages were resolved as of December 31, 2011. The average duration of shortage as of Dec-31-2011 was 589.2±304.6 days. The average number of companies marketing the products in short supply was 5.4±3.1, with 5 products having only 1 manufacturer. Generic products were available for 95.0% of the drugs. The brand name product was discontinued for 55.0% of the drugs. The drugs in shortage had an average of 2.3±1.0 shortages from 2001 to 2011. Shortages resulting from discontinuation occurred because of problems with manufacturing (35.0%), raw materials (15.0%), FDA regulatory issues (5.0%), and for unknown reasons (45.0%). **CONCLUSIONS:** Over one-fourth of the injectable systemic antibiotics available in the United States were reported in short supply. Problems with manufacturing and raw materials represented most of the reported causes of shortages. Additional research is needed to assess the risk factors and causes of pharmaceutical shortages in the United States.

### PHP13

### IMPACT OF MEDICARE PART D ON PHARMACEUTICAL AND MEDICAL UTILIZATION IN ARIZONA'S DUAL ELIGIBLE POPULATION

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**OBJECTIVES:** To estimate the impact of Medicare Part D on prescription and medical utilization among Arizona's senior dual eligible population. **METHODS:** This study was a retrospective analysis of changes in pharmaceutical utilization and physician visits among Arizona senior dual eligible (Medicaid and Medicare) beneficiaries between the ages of 66 and 80 as of January 1, 2006 relative to a comparison group (Medicaid beneficiaries between the ages of 50 and 62 as of January 1, 2006). Medical and pharmacy claims from the Medicaid program from January 1, 2005 to December 31, 2007 were used in this analysis. Differences between groups with respect to over-the-counter (OTC) medications, benzodiazepines, total prescription utilization, generic medication utilization, and physician visits were estimated using generalized estimating equations. **RESULTS:** The dual eligibles and comparison group were similar in their level and trend of utilization of over-the-counter (OTC) medications and benzodiazepines in the pre-Part D period. Following implementation of Part D, there was an immediate decline in utilization of both OTC medications and benzodiazepines in the dual eligibles relative to the comparison group ($p< 0.001$). An upward trend was observed for both groups during the pre-Part D period for total prescription utilization and generic medication utilization. After the implementation of Medicare Part D, utilization of these drug classes was significantly lower among the dual eligibles relative to the comparison group ($p<0.001$). Trends in physician office visits were similar for the entire study period. During the first month of Part D, however, the dual eligibles had a significantly larger increase in physician visits over the previous month relative to the comparison group ($p=0.001$). **CONCLUSIONS:** This study suggests that medication use for dual eligible Medicare beneficiaries was disrupted by the transition of outpatient drug benefits from Medicaid to Medicare Part D.

### PHP14

### FEDERAL ACTIONS INVOLVING HEALTH CARE FRAUD AND ABUSE (2006-2010)

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**OBJECTIVES:** Between $69 billion and $230 billion is spent on health care fraud annually. Most health care fraud cases are initiated by private citizens (*qui tam* relators), who receive up to 30% of recoveries. We reviewed recently concluded Federal health care fraud activities and compared our findings to those reported previously Kesselheim. **METHODS:** Data were from Taxpayers against Fraud and Department of Justice websites (January 2006 to October 2010). Cases pursued under the Federal False Claims Act (FCA), the most commonly employed law invoked in these investigations, were identified. Information on allegations, recoveries, and *qui tam* relator awards was abstracted. **RESULTS:** From 2006 to 2010, 116 Federal health care FCA cases were identified, mainly involving improper billing (64%), improper financial relationships (34%), and illegal marketing (18%) concluded. Most cases involved pharmaceutical manufacturers (27%), hospitals (20%), or health systems (15%). In comparison to cases without *qui tam* relators (39 cases, $1.9 billion in recoveries), those with *qui tam* relators (77 cases, $12.4 billion in recoveries) had greater mean per-case recoveries ($380 million versus $110 million for pharmaceutical cases; $42 million versus $25 million for hospital cases; and $170 million versus $34 million for health systems cases). *Qui tam* relators received $1.1 billion. Among *qui tam* relator cases closed since 2006 versus 1996-2005, cases involving hospitals and health systems decreased 84% and 30%, respectively (per-case recoveries increased 14-fold and 2.7-fold, respectively); and pharmaceutical manufacturers' cases tripled (to 34) (per-case recoveries doubled to $380 million). **CONCLUSIONS:** Since 2006, 116 health care FCA cases were settled, accounting for $14.3 billion in recoveries. *Qui tam* relators continue to play a dominant role, accounting for the majority of 70% of the cases and financial recoveries. New investigation approaches including field audits, task force investigations, and predictive modeling investigations augment *qui tam* relator led investigations.

### PHP15

### WHAT PRICE DO WE PAY FOR REPURPOSING MEDICINES FOR RARE DISEASES?

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**OBJECTIVES:** High prices of orphan medicines are a cause for concern as they put pressure on pharmaceutical budgets and may negatively influence patient access to pharmacotherapy. While repurposing of drugs is an attractive strategy to overcome the logistical and financial burden of the first phases of medicine development, we argue that repurposed medicines for rare indications, for which effectiveness evidence has already been published, do not warrant high prices. **METHODS:** We identified 16 examples of repurposed medicines for rare indications for which effectiveness evidence was published prior to the application for orphan designation and compared Belgian hospital prices between the common disease and the rare indication of the same medicine. **RESULTS:** In the majority of cases (n = 13), the pharmaceutical form of the medicine was identical for the common and for the rare indication. Medicine prices (per defined daily dose) for the rare indication were nearly the same as for the common disease for cladribine and tadalafil, and ranged from a two-fold difference (e.g. aztreonam, sildenafil) to a 200-fold difference for histamine. Three medicines had a different pharmaceutical form for the rare indication: medicines for the rare indication were at least 56 times more expensive than for the common disease. Hospital prices per dose for the rare indication were at least 23 times higher than for the common disease. **CONCLUSIONS:** This study suggests that the majority of these selected repurposed medicines for rare indications are over-priced. This pricing practice is not justified and adds to the budget impact of treating rare diseases. There is a need to individually assess repurposed medicines taking into account the costs of research and development and the costs of market access that can be attributed to